

REMARKS

Amendments to the Claims

Claims 35-61 and 63-123 are pending. The Applicants respectfully ask the Examiner to replace all prior versions and listings of claims in the present application with the listing of claims currently provided. Claims 35, 36, 60, 61, 74-77, 79, 83, 104 and 105 were amended. The Applicants hereby state that the amendments to the claims do not add new subject matter to the specification.

Amendment support for Claims 35, 36, 60, 61, 79, 83, 104 and 105 regarding "cleavage site sequence" can be found throughout the present specification, e.g., at pg. 46, lines 1-34.

Rejection Pursuant to 35 U.S.C. § 101 Obviousness-type Double Patenting

The Examiner has provisionally rejected Claims 35-39, 41-42, 44-45, 47-49, 53, 60-61, 63-64, 66-73, 78-82, 84-86, 88-95, 100-102, 106-107 and 115-119 as allegedly being unpatentable over Claims 61-63, 71-74, 76-91 and 95-96 of U.S. Patent Application 10/261,161, Fernandez-Salas, E. et al., *Cell-based FRET Assays for Clostridial Toxins* under the judicially created doctrine of obviousness-type double patenting under 35 U.S.C. § 101. While this provisional rejection is traversed, the Applicants respectfully defer responding to the rejection until allowable subject matter is indicated.

Rejection Pursuant to 35 U.S.C. § 112, ¶ 1 New Matter

The Examiner has rejected Claims 35-61 and 73-123 as allegedly containing new matter under 35 U.S.C. § 112, ¶ 1 indicating that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. Specifically, the Examiner contends that the phrase "cleavage site region" recited by Claims 35-36, 60-61, 79, 83 and 104-105 does not appear in the present specification or in the originally filed claims, and the Applicants have failed to point out a

specific basis for this claim limitation in the present specification. The Applicants respectfully ask for reconsideration under 37 C.F.R. § 1.111.

Amended Independent Claims 35, 60, and 79 recite the phrase "cleavage site sequence." Support for this phrase can be found throughout the present specification, such as, *e.g.*, at pg. 46, lines 1-34. Claims 36, 61, 83, 104 and 105 all derive dependency from one of Claims 35, 60, and 79, and as such incorporate by reference the phrase "cleavage site sequence."

Therefore, the Applicants respectfully submit that Claims 35-61 and 73-123 are fully supported by the present specification and request withdrawal of the 35 U.S.C. § 112, ¶1 new matter rejection.

Rejection Pursuant to 35 U.S.C. § 112, ¶ 2 Definiteness

The Examiner has rejected Claims 35-61 and 73-123 as allegedly being indefinite under 35 U.S.C. § 112, ¶ 2 arguing that these claims fail to particularly point out and distinctly claim the subject matter of the claimed invention. Specifically, the Examiner contends that Claims 35-36, 60-61, 79, 83 and 104-105 are rendered vague and indefinite by the phrase "cleavage site region." The Applicants respectfully ask for reconsideration under 37 C.F.R. § 1.111.

Amended Independent Claims 35, 60, and 79 recite the phrase "cleavage site sequence." Support for this phrase can be found throughout the present specification, such as, *e.g.*, at pg. 46, lines 1-34. Claims 36, 61, 83, 104 and 105 all derive dependency from one of Claims 35, 60, and 79, and as such incorporate by reference the phrase "cleavage site sequence."

Therefore, the Applicants respectfully submit that Claims 35-61 and 73-123 particularly point out and distinctly claim the subject matter of the presently claimed invention and request withdrawal of the 35 U.S.C. § 112, ¶2 indefinite rejection.

CONCLUSION

For the above reasons the Applicants respectfully submit that the claims are in condition for allowance, and the Applicants respectfully urge the Examiner to issue a Notice to that effect. Should there be any questions, the Examiner is invited to call the undersigned agent. Please use Deposit Account 01-0885 for the payment of any extension of time fees under 37 C.F.R. § 1.136 or any other fees due in connection with the current response.

Respectfully submitted,

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